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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,033	03/22/2004	Gottfried Kellermann	3978	1008
23474 7590 03/21/2008 CLEMENTS BERNARD MILLER 1901 ROXBOROUGH ROAD SUITE 300 CHARLOTTE, NC 28211				
EXAMINER				
WANG, SHENGJUN				
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
03/21/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/806,033

**Applicant(s)**

KELLERMANN, GOTTFRIED

**Examiner**

Shengjun Wang

**Art Unit**

1617

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt of applicants' amendments and remarks submitted December 26, 2007 is acknowledged.

#### *Claim Rejections 35 U.S.C. 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al. (WO 98/48785); Lang et al. (US 6,541,043) and Kumagai et al. (WO 02/100393, EP 1 393 725 is an English equivalence).

3. Blum teaches method of treatment of reward deficit syndromes (RDS), including attention deficit disorder (ADD) and attention deficit hyperactive disorder (ADHD).

See particularly pages 34-35, 43-44. The method comprises the administration to the patients an effective dose of one or more of enkephalinase inhibitors, enkephalin releasers and amino acid precursors for the dopaminergic system. 5-hydroxytryptophan, phenylalanine, glutamine, taurine and tyrosine are particularly listed as useful agents. See, particularly, pages 100-126.

Lang et al. teaches that 5-hydroxytryptophan and tyrosine are particularly useful for treatment of ADHD, especially in combination with other agent known to be useful for treatment of ADHD. See, particularly, the abstract, and the claims. Kumagai et al. teaches that theanine is particularly useful for treatment of ADHD. See, particularly, the abstract, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use 5-hydroxytryptophan, theanine, tyrosine, phenylalanine, taurine and glutamine for treatment of ADHD.

A person of ordinary skill in the art would have been motivated to use 5-hydroxytryptophan, theanine, tyrosine, phenylalanine, taurine and glutamine for treatment of ADHD because all the compounds are known to be useful for the treatment of ADHD. Note it is prima facie obvious to combine two or more compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069. As to the particular schedules for administration of those known agents, note the optimization of a result effective parameter, e.g., therapeutic dosage and duration, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Since all the compounds herein are taught to be useful for treatment of ADHD, the employment of certain combination of any of those compounds for certain period of time would be within the general teaching of the prior art and is deemed to be an obvious variants of therapeutic regimen. In the instant case, Applicants attempt to capture these obvious variants of the old and well known therapeutic method. Absent an illustration of unexpected benefits residing in the specific combination and schedule herein claimed, the instant claims remain properly rejected under 35 USC 103.

***Response to the Arguments***

Applicants' amendments and remarks submitted December 26, 2007 have been fully considered, but are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching, suggestion and motivation are found in the cited references and in the knowledge generally available to one of ordinary skill in the art. Particularly, the references teach each and every ingredients herein employed is useful for treatment of ADHD, the employment of the combination of them would have been obvious for reasons as set forth in See *In re Kerkhoven*, 205 USPQ 1069.

Applicants also assert that the claimed invention "obtains successful results as illustrated by the examples in applicant's specification which represent unexpected benefits of the present invention." The arguments are untenable. The application provide no evidence showing unexpected benefit that commensurate in scope of claimed invention.

Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d).

Further, A DECLARATION UNDER 37 CFR 1.132 must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case of obviousness. See, MPEP 716.02 (c).

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/  
Primary Examiner, Art Unit 1617